MAY 15 2002

K020840

PREMARKET NOTIFICATION 510(K) SUMMARY

Applicant: Vital Scientific NV
One Gateway center
Suite 411
Newton, MA 02458
1(617) 527-9933 Ext 42
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Contact: Israel M. Stein MD

Date: March 14, 2002

Device Name: Vital Scientific PT with Calcium
Quik Coag PT with Calcium
Vital Scientific PT
PT with Calcium

Common Name: Prothrombin Time Test

Classification Name: Prothrombin Time Test, 21 CFR section 864.7750 (GJS)

Comparison Device: Instrumentation Laboratory Inc.
IL Test PT-Fibrinogen HS (K981479)

Description of the Device and Intended Use

The Vital Scientific PT with Calcium is an *in vitro* diagnostic test intended for use for the performance of Prothrombin Time (PT) testing and quantitative PT-based factor assays (for Factors II, V, VII and X). The test is used for the quantitative determination of blood clotting factors in the extrinsic pathway, (VII), and common pathway (II, V and X) of coagulation. The capacity of blood to form a fibrin clot by way of the extrinsic haemostatic pathway requires thromboplastin, calcium, factors VII, V, X, II and I. The Vital Scientific PT with Calcium consists of a lyophilized extract of rabbit brain thromboplastin calcium salt, buffers and stabilizers.

Summary of Substantial Equivalence Comparisons

The Vital Scientific PT with Calcium is substantially equivalent in intended use and performance to Instrumentation Laboratory IL Test PT-Fibrinogen HS (K981479).

Both the predicate device and the proposed product are formulated to detect deficiencies in factors II, V, VII and X (PT and PT-based factor assays). Both are *in vitro* tests which can be used for monitoring oral anticoagulant therapy.

In correlation studies, PT testing of specimens from normal and abnormal patients, as well as samples from patients receiving anti-coagulant therapy, were tested using both reagent devices at a community hospital and yielded a correlation coefficient 0.92. The average values of the elevated PT samples were within one standard deviation of the predicate device average.

The systematic bias was eliminated when the results were converted to INR. The correlation using INR values, which corrects for differences in reagent sensitivity, shows a slope of 1.01 and the intercept 0.01. This indicates that the PT reagents provide the same INR value as any other calibrated PT reagent.

Within-run and between run precision studies were performed and CV's of less than 1% were obtained for the proposed device.

Vital Scientific NV, submits that the Vital Scientific PT with Calcium has the same intended use, a similar technological principle, and clinically acceptable performance comparable to similar devices currently in commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 15 2002

Israel M. Stein, M.D.
Managing Director
Vital Scientific
One Gateway Center, Suite 415
Newton, Massachusetts 02458

Re: k020840
Trade/Device Name: Vital Scientific PT with Calcium
Regulation Number: 21 CFR § 864.7750
Regulation Name: Prothrombin Time Test
Regulatory Class: II
Product Code: GJS
Dated: March 14, 2002
Received: March 15, 2002

Dear Dr. Stein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K 020840

Device Name: **Vital Scientific PT**

Indications For Use:

The Vital Scientific PT with Calcium is an *in-vitro* diagnostic reagent intended for use for the performance of one-stage Prothrombin Time (PT) Testing and assays which are based on a modified prothrombin time.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Josephine Bautista

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020840

Prescription Use (Per 21 CFR 801.109) OR Over-The-Counter Use (Optional Format 1-2-96)